Remarks

Applicants have amended claims 1, 2, 5, 12, 13 and 16. Support for these amendments may be found in the application as filed. Applicants submit that these amendments place the claims in condition for allowance. No new matter has been added.

The Objections

Regarding the objection to the drawings made in paragraph 6, applicants will submit formal drawings upon receipt of the Notice of Allowability, as set forth in 37 C.F.R. § 1.85.

The Rejections

Applicants gratefully acknowledge the Examiner's withdrawal of rejections as set forth in paragraphs 7-12 of the January 28, 2005 office communication.

35 U.S.C. § 112, second paragraph

The Examiner has rejected claims 2, 4-10, 12, 13, 15 and 16 as indefinite. Applicants have amended these claims, as suggested by the Examiner, as follows.

Claim 2 has been amended to recite "the peptide mimic comprises the amino acid sequence of SEQ ID NO:8."

Claim 5 has been amended such that "said sequence" now recites "said amino acid sequence."

Claim 16 has been amended to recite "peptide mimic comprising the amino acid sequence."

Claims 12 and 13 have been amended to recite immunospecific binding to the monoclonal antibody.

Claim 13 has been amended to recite "antigen-binding fragment thereof." Support for this amendment can be found, for example, in the specification at page 6, lines 9-19. One of skill in the art as of the filing date of the application was aware of the kinds of fragments that retain the antigen-binding portion of the molecule, such as Fab, Fab', $F(ab)_2$ and F(v) fragments. One of skill in the art was aware that to achieve immunospecific binding, it is important to retain the complementarity determining regions in any antibody fragment.

Claim 13 has also been amended to recite "hybridoma cell line HB 11311."

For the above reasons, applicants respectfully request that the Examiner withdraw the 35 U.S.C. § 112, second paragraph rejections.

35 U.S.C. § 102

Magdalene *et al.*

The Examiner has rejected claims 1, 3-6, 8 and 15 under 35 U.S.C. § 102(b) as being anticipated by Magdalene *et al.* (WO 85/04654). Applicants traverse.

The peptides described in Magdalene *et al.* are intended to be smaller than the pilin protein but nevertheless derived from it. Such peptides are not the same as applicants' peptides, which are designed to mimic a conserved lipo-oligosaccharide epitope. One of skill in the art would not equate peptides representing pilin protein epitope structure with applicants' claimed peptides representing the 2C7 lipo-oligosaccharide epitope structure.

Moreover, as discussed in applicants' specification, the immune response elicited by pilin immunization is predominantly a humoral one. Even though IgG is produced, it is primarily IgG3, with lesser amounts of IgM and IgA (see specification at page 3, lines 11-25). Indeed, applicants' specification discusses the shortcomings of prior art pilin vaccines (see page 4, line 29 through page 5, line 9).

Applicant has amended claim 1 to clarify that the claimed peptides function to mimic a conserved lipo-oligosaccharide (LOS) gonococcal epitope. Therefore the pilin peptides of Magdalene *et al.*, by definition, do not anticipate applicants' amended claims.

Kufer *et al.*

The Examiner has rejected claims 1, 2, 10, 12, 13 and 15 under 35 U.S.C. § 102(b) as being anticipated by Kufer *et al.* (WO 98/46645). Applicants traverse.

Kufer *et al.* relates to the development of antibody-like molecules that act as receptors for human tumor antigens (see Kufer *et al.* page 1, second full paragraph). The peptides listed in Kufer *et al.* were designed as mimics of the human tumor antigen 17-1A, also known as EpCAM. The Kufer *et al.* work is in a field wholly unrelated to gonococcal epitope immunization.

Applicants have not claimed the bare consensus sequence of SEQ ID NO:8, DE_GLF. While applicants have taught that this consensus sequence is correlated with the capacity to induce a specific anti-gonococcal immune response, peptides bearing this consensus sequence may exist that are not capable of inducing in a mammal an immune response against a

conserved gonococcal lipo-oligosaccharide (LOS) epitope. Because the Kufer *et al.* peptides have never been tested for their immunogenic properties as they relate to gonococcal epitopes, Kufer *et al.* cannot be said to unambiguously anticipate the claim limitation "capable of inducing in a mammal an immune response against a conserved gonococcal lipo-oligosaccharide (LOS) epitope."

Because the Kufer *et al.* peptide in question does not unambiguously satisfy every limitation of applicants' claims, it cannot anticipate those claims.

For these reasons, the rejections under 35 U.S.C. § 102 may properly be withdrawn.

35 U.S.C. § 103

The Examiner has rejected claims 6 and 7 under 35 U.S.C. § 103 as obvious in view of Magdalene *et al.* and Clements.* Applicants traverse.

As discussed above, the pilin peptides of Magdalene *et al.* are not related to LOS epitopes and do not fall within applicants' claims. For this reason alone, Magdalene *et al.* does not render claims 6 and 7 obvious.

The approach of Magdalene *et al.* involved the use of small fragments of the pilin nominal antigen. Pilin is itself a protein, and proteins are generally considered good candidates for use as immunogens. LOS, on the other hand, is generally viewed as a weaker

* Clements, J.D., "Construction of a Nontoxic Fusion Peptide for Immunization against *Escherichia coli* Strains That Produce Heat-Labile and Heat-Stable Enterotoxins," *Inf. Immun.* 58:1159-66 (1990).

immunogen, and one of skill in the art therefore would not have been motivated to employ fragments of LOS as an immunogen. Even if one had used LOS fragments, this would not render applicants' claims 6 and 7 obvious because there is no suggestion in Magdalene *et al.* to take a lipo-oligosaccharide antigen and somehow convert it into a peptide mimic, as applicants have done.

Indeed, because of this extra step of converting a lipo-oligosaccharide antigen into a peptidic version, one of skill in the art would not have had a reasonable expectation of successfully achieving the claimed invention. It is simply too far a distance from the pilin fragments of Magdalene *et al.* to applicants' peptide versions of a conserved LOS epitope. Because of this fundamental difference, one of skill in the art would not have had a reasonable expectation of success in achieving an LOS peptide mimic, let alone one that is capable of inducing an immune response against the conserved LOS epitope.

Clements does not provide the missing suggestion or expectation of success.

The Examiner has rejected claim 9 under 35 U.S.C. § 103 as obvious in view of Magdalene *et al.* and Tam* or Huang *et al.*** Applicants traverse.

As discussed above, the peptides of Magdalene *et al.* are not the same as applicants' claimed LOS peptide mimics. Nor does Magdalene *et al.* provide a suggestion to

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* Tam, "Peptide Antigens: A Practical Approach," Wisdom, G.B., Ed. IRL Press; Oxford Univ. Press:New York, pp. 83-90 (1994).

** Huang *et al.*, "Lipophilic multiple antigen peptide system for peptide immunogen and synthetic vaccine," *Mol. Immunol.* 31:1191-99 (1994).

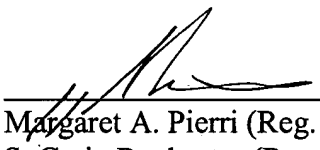
make peptide versions of any conserved gonococcal LOS epitope. And Magdalene *et al.* does not provide a reasonable expectation of arriving at such a peptide LOS mimic, nor does it provide a reasonable expectation of achieving such a peptide LOS mimic that is capable of inducing an immune response against the conserved LOS epitope.

Neither Tam nor Huang *et al.* provide the missing suggestion and expectation of success.

CONCLUSION

In view of the foregoing remarks, applicants request that the Examiner favorably consider this application and allow the claims pending herein.

Respectfully submitted,



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